

Docket No.: CI-000



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Shirley I. MIEKKA et al.

Serial No.: 09/942,941

: Group Art Unit: 2881

Filed: August 31, 2001

: Examiner: Unassigned

For: METHODS FOR STERILIZING
PREPARATIONS CONTAINING
ALBUMIN

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TECHNOLOGY CENTER 2800

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).

— 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).

— a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

X 4. The relevancy of the non-English language references can be determined from the attached abstracts.

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
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MLF:DRM:kpc

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SHEET 1 OF 13

LIST OF PRIOR ART CITED BY
APPLICANT
(PTO-1449)

ATTY. DOCKET NO. CI-0003	APPLN. SERIAL NO. 09/942,941
APPLICANT Shirley I. MIEKKA et al.	
FILING DATE August 31, 2001	GROUP 2881

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	RE 23,195	02/1950	Arno Brasch			
	2,832,689	04/1958	Bernard E. Proctor et al.			
	2,920,969	01/1960	E.S. Stoddard			
	2,962,380	11/1960	J.H. Wertheim			
	3,620,944	11/1971	Keiko Tanito			
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						Yes	No
	2,056,619	10/1991	Canada				
	310 316	04/1989	Europe (Abstract)			X	
	334 679	09/1989	Europe (Abstract)			X	
	919 918 A2	06/1999	Europe (Abstract)			X	
	919 918 A3	06/1999	Europe (Abstract)			X	

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AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14
Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19
Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<p style="text-align: center;">LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)</p> <p style="text-align: center;">APR 18 2002 JC78</p> <p style="text-align: center;"><i>EXAMINER'S TRADEMARK OFFICE</i></p>				ATTY. DOCKET NO. CI-0003	APPLN. SERIAL NO. 09/942,941	
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	4,370,264	01/1983	Kotitschke et al.			
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	4,620,908	11/1986	Van Duzer			
	4,865,602	09/1989	Smestad et al.			
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FOREIGN PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	11-216147	08/1999	Japan (Abstract)			<input checked="" type="checkbox"/> X
	1321420-A	07/1987	Soviet Union (Abstract)			<input checked="" type="checkbox"/> X
	WO 90/00907	02/1990	PCT Int'l (Abstract)			<input checked="" type="checkbox"/> X
	WO 91/16060	10/1991	PCT Int'l (Abstract)			<input checked="" type="checkbox"/> X
	WO 95/03071	02/1995	PCT Int'l (Abstract)			<input checked="" type="checkbox"/> X
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	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214					
	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41					
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	5,226,065	07/1993	Held et al.			
	5,362,442	11/1994	Kent			
	5,418,130	05/1995	Plat. et al.			
	5,460,962	10/1995	Kemp			
	5,510,122	04/1996	Sreebny et al.			
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	5,637,451	06/1997	Ben-Hur et al.			
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	5,712,086	01/1998	Horowitz et al.			
	5,730,933	03/1998	Peterson			
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EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes No
	WO 00/25839	03/2000	PCT Int'l (Abstract)			X
	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X
	WO 01/12318A1	02/2001	PCT Int'l (Abstract)			X
	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X
	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X
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	S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115					
	J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19					
	Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks					
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LIST OF PRIOR ART CITED BY APPLICANT <small>APR 18 2002</small> <small>578</small> <small>(PTO-1449)</small>				ATTY. DOCKET NO. CI-0003	APPLN. SERIAL NO. 09/942,941	
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	5,837,313	11/1998	Ding et al.			
	5,881,534	03/1999	Ahlqvist et al.			
	5,981,163	11/1999	Horowitz et al.			
	5,986,168	11/1999	Noishiki			
	6,046,024	04/2000	Burton et al.			
	6,049,025	04/2000	Stone et al.			
	6,066,626	05/2000	Yew et al.			
	6,087,141	07/2000	Margolis-Nunno et al.			
	6,120,592	09/2000	Brault et al.			
	6,159,490	12/2000	Deghenghi			
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	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
FOREIGN PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes <input type="checkbox"/> No <input type="checkbox"/>
	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X
	WO 01/49219A1	07/2001	PCT Int'l (Abstract)			X
	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X
	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X
	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X
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	6,187,572	02/2001	Platz et al.			
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	6,203,544	03/2001	Gotzen			
	6,214,534	04/2001	Horowitz et al.			
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	4,784,850	11/1998	Abraham			
	4,798,611	01/1989	Freeman, Jr.			
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	Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33					
	A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps.					
	337-330, Thorac. Cardiovasc. Surgeon, Vol. 42					
	David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001					
	pps. 69-76, Journal of Neurochemistry, Vol. 76					
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<p>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</p> <p>P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102</p> <p>P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39</p> <p>Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5</p> <p>P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38</p> <p>D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69</p> <p>Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2</p> <p>A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254</p> <p>Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, 1995, pps. 406 (Abstract)</p> <p>P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4</p> <p>R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28</p> <p>Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20</p> <p>Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4</p> <p>Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. 5</p> <p>Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7</p> <p>Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222</p> <p>M.J. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2</p>		
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